

§ 510.440

Warning: Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca.

[49 FR 48535, Dec. 13, 1984]

§ 510.440 Injectable iron preparations.

There has been an increasing interest in the use of injectable iron compounds for the prevention or treatment of iron-deficiency anemia in animals. Although some such preparations have been shown to be safe, such articles are regarded as new animal drugs within the meaning of the Federal Food, Drug, and Cosmetic Act. Accordingly, an approved new animal drug application is required prior to the marketing of such preparations within the jurisdiction of the act. In addition to the need for demonstrating the safety of such articles, the labeling of such preparations should not only recommend appropriate dosages of iron but also declare the amount (in milligrams) of available iron (Fe) per milliliter of the subject product.

§ 510.455 Requirements for free-choice medicated feeds.

(a) *What is free-choice medicated feed?* For the purpose of this part, free-choice medicated feed is medicated feed that is placed in feeding or grazing areas and is not intended to be consumed fully at a single feeding or to constitute the entire diet of the animal. Free-choice feeds include, but are not limited to, medicated blocks (agglomerated feed compressed or rendered into a solid mass and cohesive enough to hold its form), mineral mixes, and liquid feed tank supplements ("lick tank" supplements) containing one or more new animal drugs. The manufacture of medicated free-choice feeds is subject to the current good manufacturing practice regula-

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tions in part 225 of this chapter for medicated feeds.

(b) *What is required for new animal drugs intended for use in free-choice feed?* Any new animal drug intended for use in free-choice feed must be approved for such use under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(b)) or listed in the index under section 572 of the act (21 U.S.C. 360ccc-1). Such approvals under section 512 of the act must be:

- (1) An original new animal drug application (NADA),
- (2) A supplemental NADA, or
- (3) An abbreviated NADA.

(c) *What are the approval requirements under section 512 of the act for new animal drugs intended for use in free-choice feed?* An approval under section 512 of the act for a Type A medicated article intended for use in free-choice feed must contain the following information:

(1) Data, or reference to data in a master file (MF), showing that the target animal consumes the new animal drug in the Type C free-choice feed in an amount that is safe and effective (consumption/effectiveness data); and

(2) Data, or reference to data in an MF, showing the relevant ranges of conditions under which the drug will be chemically and physically stable in the Type C free-choice feed under field conditions.

(d) *How are consumption/effectiveness and/or stability data to be submitted?* The data must be submitted as follows:

- (1) Directly in the NADA, by a sponsor; and/or
- (2) To an MF that a sponsor may then reference in its NADA with written consent of the MF holder.

(e) *What will be stated in the published approval for a new animal drug intended for use in free-choice feed?* The approval of a new animal drug intended for use in free-choice feed, as published in this subchapter, will include:

(1) The formula and/or specifications of the free-choice medicated feed, where the owner of this information requests such publication, or

(2) A statement that the approval has been granted for a proprietary formula and/or specifications.

(f) *When is a medicated feed mill license required for the manufacture of a free-*

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choice medicated feed? An approved medicated feed mill license is required for the manufacture of the following types of feeds:

- (1) All free-choice medicated feeds that contain a Category II drug, and
- (2) Free-choice medicated feeds that contain a Category I drug and use a proprietary formula and/or specifications.

[69 FR 30197, May 27, 2004, as amended at 72 FR 69121, Dec. 6, 2007]

Subpart F [Reserved]

Subpart G—Sponsors of Approved Applications

\$510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

(a) Section 512(i) of the act requires publication of names and addresses of

sponsors of approved applications for new animal drugs.

(b) In this section each name and address is identified by a numerical drug labeler code. The labeler codes identify the sponsors of the new animal drug applications associated with the regulations published pursuant to section 512(i) of the act. The codes appear in the appropriate regulations and serve as a reference to the names and addresses listed in this section. The drug labeler code is established pursuant to section 510 of the act.

(c) The names, addresses, and drug labeler codes of sponsors of approved new animal drug applications are as follows:

(1) ALPHABETICAL LISTING OF SPONSORS

Firm name and address	Drug labeler code
A & G Pharmaceuticals, Inc., 1030 West Commodore Blvd., Jackson, NJ 08527	057699
AB Science, 3 Avenue George V, 75008 Paris, France	052913
Abbott Laboratories, North Chicago, IL 60064	000074
ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115	012286
Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464	024174
Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503	057561
Agri-Tech, Inc., 4722 Broadway, Kansas City, MO 64112	017762
Alaco, Inc., 1500 North Wilmot Rd., suite 290-C, Tucson, AZ 85712	064146
Alpharma, LLC, a wholly owned subsidiary of Pfizer, Inc., 235 East 42d St., New York, NY 10017	046573
Alstoe, Ltd., Animal Health, Pera Innovation Park, Nottingham Rd., Melton Mowbray, Leicestershire, England LE13 0PB	062408
American Pharmaceuticals and Cosmetics, Inc., 1401 Joel East Rd., Fort Worth, TX 76140	065531
Anika Therapeutics Inc., 236 West Cummings Park, Woburn, MA 01801	060865
Argent Laboratories, 8702 152d Ave. NE., Redmond, WA 98052	051212
Ark Sciences, Inc., 1101 East 33rd St., suite B304, Baltimore, MD 21218	076175
B.L. Mitchell, Inc., 103 Hwy. 82 E., Leland, MS 38756	067188
Baxter Healthcare Corp., 95 Spring St., New Providence, NJ 07974	010019
Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201	000859
Belcher Pharmaceuticals, LLC, 6911 Bryan Dairy Rd., Largo, FL 33777	062250
Bioniche Animal Health USA, Inc., 119 Rowe Rd., Athens, GA 30601	064847
Bioniche Teoranta, Inverin, County Galway, Ireland	063286
Bioproducts, Inc., 320 Springside Dr., Suite 300, Fairlawn, OH 44333-2435	051359
BioScience Division of Milk Specialties Co., 1902 Tennyson Lane, Madison, WI 53704	032761
Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506-2002	000010
Cephazone Pharma, LLC, 250 East Bonita Ave., Pomona, CA 91767	068330
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland	061651
ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105	021091
Contemporary Products, Inc., 3788 Elm Springs Rd., Springdale, AR 72764-6067	055462
Cooperative Research Farms, Box 69, Charlottesville, NY 12036	051267
Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland	061623
Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501	046987
Dechra, Ltd., Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, United Kingdom	043264
ECO LLC, 8209 Hollister Ave., Las Vegas, NV 89131	066916
Eka Chemicals, Inc., 1775 West Oak Commons Ct., Marietta, GA 30062-2254	061088
Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285	000986
Endo Pharmaceuticals, Inc., 100 Painters Dr., Chadds Ford, PA 19317	060951
Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013-3928	017135
First Priority, Inc., 1590 Todd Farm Dr., Elgin, IL 60123	058829
Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234	015565